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| (51) International Patent Classification ⁶ : A01N 37/18, A61K 38/00, 38/16, A23D 7/00, 9/00, A23G 3/00, A23J 1/00, A23L 1/30, 2/00, A23K 1/175, B01F 15/02, G05D 11/00 | A1 | (11) International Publication Number: WO 98/21953 (43) International Publication Date: 28 May 1998 (28.05.98) |
| (21) International Application Number: PCT/US97/21303 (22) International Filing Date: 20 November 1997 (20.11.97) (30) Priority Data: 08/754,605 20 November 1996 (20.11.96) US (71) Applicant: CROWN LABORATORIES, INC. [US/US]; 6780 Caballo Street, Las Vegas, NV 89119 (US). (72) Inventors: NASH, Scott, Oldham; 678 Cervantes Drive, Henderson, NV 89014 (US). NASH, Craig, Emery; Apartment 234, 230 E. Flamingo Road, Las Vegas, NV 89109 (US). PARK, Peter, S., W.; 1985 Waverly Circle, Henderson, NV 89014 (US). (74) Agent: WALDBAUM, Maxim, H.; Fried, Frank, Harris, Shriver & Jacobson, One New York Plaza, New York, NY 10004 (US). | (81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> | |
| (54) Title: IMPROVED LIQUID NUTRITIONAL SUPPLEMENT AND ASEPTIC PROCESS FOR MAKING SAME (57) Abstract <p>An improved nutritional supplement and aseptic process for making same is provided. The liquid nutritional supplement provides improved concentration of many recommended both macro- and micro-nutrients in a shelf-stable form. A process for making the improved nutritional supplement is also provided, in which the supplement is subjected to higher-pressure homogenization of the supplement after ultra-high temperature turbulent flow sterilization. The improved nutritional supplement of the present invention provides a higher level of nutrients with many recommended minerals and vitamins in a smaller volume than supplements not having the high level of total solids of the liquid nutritional supplement of the present invention. The supplement also has an improved mouth feel, flavor profile and taste, resulting in higher intake of the supplement, especially beneficial for effective nutritional management of consumers with comprised stomach capacity.</p> | | |

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**IMPROVED LIQUID NUTRITIONAL SUPPLEMENT AND
ASEPTIC PROCESS FOR MAKING SAME**

Background Of The Invention

The present invention is directed to an improved nutritional supplement and process for making same, and more particularly, to a liquid nutritional supplement which provides improved concentration of many recommended macro- and micro-nutrients in a shelf-stable form. The present invention is also directed to a process for improving the shelf-stability and flavor profile of a liquid nutritional supplement, in which the supplement undergoes ultra-high temperature (UHT) processing while flowing through the UHT processor in a turbulent state and is then subjected to higher-pressure homogenization.

Currently, there are several liquid nutritional supplements available on the market, which have found application in many areas, including as a meal supplement or a meal replacement. The supplements contain enhanced levels of protein, fat, carbohydrate, vitamins and minerals which may benefit the consumers of the supplements in accomplishing balanced nutrition and thus maintain a good health. They are flavored and homogenized to improve their appearance, flavor profiles and taste, which are important factors in consumer acceptability and commercial success of the supplement. Supplements of this type include ENSURE and PULMOCARE brands from Ross Laboratories, a division of Abbott Laboratories, SUSTACAL and TRAUMACAL brands from Mead Johnson & Co., and RESOURCE from Sandoz Ltd. These supplements generally have a total solids content under 30% by total weight of the supplement, and thus have an large excess of water as compared to the amount of water necessary to solubilize the components of the supplement.

Nutritional supplements on the market today are available in no less than 8 or 10 ounce sizes, and in order to obtain the full benefit of the dietary supplement it must be entirely consumed. However, as a result of age-related and other factors, some people often have an undersized stomach and reduced appetite, so that the total volume of liquid and solid food which can be consumed is limited. An example of a patent directed to a higher-volume dietary supplement is U.S. Patent No. 4,497,800 to Larsen et al.

In addition, the presence of high levels of nutrients, especially minerals, while essential to the effectiveness of a nutritional supplement, has a counterproductive effect on the solubility of the components of the supplement and the consistency of the resulting liquid. In particular, the components can separate out into organic and aqueous phases, and minerals

1 can settle out of the liquid to form sedimentation on the bottom of the container during the
2 expected shelf life of the packaged supplement. Such separation and sedimentation are
3 undesirable for a number of reasons. One, it is visually unappealing to intended consumers
4 of the supplement, and reduces the likelihood that the supplement will be fully consumed.
5 Second, it reduces the efficacy of the supplement, if the minerals have settled out of the liquid
6 being consumed and hardened into a nondispersible form.

7
8 The liquid nutritional supplement must also be sterilized so that it will be
9 "commercially sterile," or safe for human consumption during its expected shelf life.
10 Conventionally, liquid nutritional supplements have been sterilized through the use of a post-
11 packaging retorting process, in which a homogenized liquid mixture of nutrients is packaged
12 in a hermetically sealed container and then the container is subjected to steam heating under
13 pressure for an extended period of time equivalent to approximately 5-10 minutes at 121 °C.
14 From the onset of steam-on to steam-off, this process could take 20-60 minutes to accomplish
15 commercial sterility. This retorting process is abusive to the container itself as well as the
16 heat-sensitive nutrients of liquid nutritional supplements, and may accelerate the process of
17 separation and sedimentation discussed above. It also exerts an adverse effect on the aroma
18 and taste of the final product. U.S. Patent No. 4,497,800 to Larsen et al. is one example of a
19 supplement sterilized by this retorting process.

20
21 Another method for sterilizing certain types of nutritional formulations is referred to
22 as continuous thermal or UHT (ultra-high temperature) processing, also known as aseptic
23 processing. UHT processing can be accomplished by direct injection of steam into the liquid
24 to be sterilized, or by indirect heating of the liquid as it flows through a tube surrounded by
25 steam or past a heat exchanger plate. The raw product is sterilized before being packaged in
26 previously sterilized containers. In this aseptic process, the product mixture is subjected to
27 brief but intense heating in the temperature range of 130-145 °C, for a time sufficient to
28 commercially sterilize the product, approximately 2-45 seconds. The use of UHT processing
29 to sterilize a certain kind of nutritional formulation having a high acidity and primarily using
30 whey as the protein component of the nutritional supplement is discussed in U.S. Patent No.
31 5,520,948 to Kvamme. The use of UHT processing in the preparation of a liquid nutritional
32 supplement requiring the use of high proportion of a certain kind of stabilizer, iota-
33 carrageenan, to maintain shelf stability is taught in U.S. Patent No. 5,416,077 to Hwang et al.

34
35 The use of UHT processing is also known in the preparation of infant formula, dairy
36 products, and non-dairy creamers, which all have much lower levels of nutrients than the
37 nutritional supplements. Examples include U.S. Patent No. 4,748,028 to McKenna et al; U.S.

1 Patent No. 4,851,243, U.S. Patent No. 4,888,194, and U.S. Patent No. 4,9335,255, all to
2 Anderson et al.; and U.S. Patent No. 5,378,488 to Dimler et al.

3
4 The use of UHT processing in conventional low-acid liquid nutritional supplements
5 using milk proteins such as caseinates as their protein source has encountered a number of
6 difficulties. These difficulties are caused in part by the localized build-up of heat within the
7 supplement during UHT processing. They are also caused in part by the high levels of micro-
8 nutrient minerals present in the supplement, combined with the high levels of sources of
9 protein and fat macro-nutrients. These difficulties include nonenzymatic browning, or "burn
10 on", which causes an undesirable color and unpleasant flavor. In addition, fouling of the
11 processing tubing has been encountered, caused by sedimentation and separation of the
12 components during UHT sterilization. In an attempt to reduce the likelihood that minerals
13 will separate out of the supplement during ultra high temperature processing, prior art
14 supplements sterilized using this technique use if possible water-soluble compounds as
15 sources of minerals. For example, ferrous sulfate is used as a source of iron.

16
17 As a result of the presence of both hydrophobic and hydrophilic components in the
18 liquid nutritional supplement, they are conventionally subjected to homogenization during
19 processing. This improves the shelf stability as well as the flavor profile and appearance of
20 the final liquid nutritional supplement. However, this homogenization is usually performed
21 prior to UHT sterilization at pressures not exceeding 2,500 pounds per square inch (psi),
22 based on experience gained in homogenization of dairy products.

23
24 In light of the above, it would be desirable to provide a liquid nutritional supplement
25 which provides improved concentration of many recommended macro- and micro-nutrients in
26 a shelf-stable form. It would also be desirable to provide a fully aseptic sterilization and
27 homogenization process for a liquid nutritional supplement resulting in improved shelf-
28 stability and flavor profile.

29 30 SUMMARY OF THE INVENTION

31 In accordance with the present invention, there is provided an improved liquid
32 nutritional supplement which provides improved concentration of many recommended
33 nutrients in a shelf-stable form. As used herein, a liquid nutritional product is "shelf-stable"
34 if it is essentially devoid of separation or sedimentation over the expected shelf life of the
35 product.

36
37 The liquid nutritional supplement comprises:

1 (a) a macro-nutrient component comprising 22 to 150 milligrams of protein
2 and 30 to 200 milligrams of fat per milliliter of supplement; and
3 (b) a mineral micro-nutrient component comprising 1.5 to 10 milligrams of
4 potassium; 0.4 to 2.97 milligrams of calcium; 0.17 to 1.18 milligrams of
5 magnesium; 0.42 to 2.97 milligrams of phosphorus; and 0.015 to 0.053
6 milligrams of iron per milliliter of supplement;
7 wherein the nutritional supplement is commercially sterile and shelf-stable.

8
9 In another aspect of the present invention, the commercially sterile and shelf-stable
10 liquid nutritional supplement comprises:

- 11 (a) a macro-nutrient component comprising at least one source of protein, at
12 least one source of fat, and at least one source of carbohydrate,
13 (b) a mineral micro-nutrient component comprising at least one source of
14 mineral micro-nutrients which is virtually water-insoluble, and
15 (c) a stabilizer,

16 wherein the total solids present in the supplement is not less than 30% of the total
17 weight of the supplement.

18
19 In an additional aspect of the invention, the liquid nutritional supplement is sterilized
20 by continuous thermal processing at ultra-high temperature and comprises as a source of iron
21 ferric ortho-phosphate.

22
23 One aspect of the invention is a process for maintaining emulsion stability and
24 extending the shelf life of a liquid nutritional supplement formulated as an emulsified slurry
25 comprising sources of macro-nutrients and then sterilized, comprising the step of passing the
26 emulsified slurry through a pump exerting a hydroshear of between 100 to 250 pounds per
27 square inch.

28
29 In another aspect of the present invention, a process for aseptically sterilizing and
30 homogenizing a liquid nutritional supplement comprises the steps of:

- 31 (a) heating the supplement to a temperature of at least 130 °C for a time
32 sufficient to commercially sterilize the supplement while the supplement is
33 passing through a hold tube under a pressure sufficient to keep the flow of the
34 supplement through the hold tube substantially turbulent;
35 (b) passing the supplement through a remote aseptic homogenizer having at
36 least one valve creating a pressure of at least 2,800 pounds per square inch

1 wherein the valve also acts as a pressure restrictor on the supplement flow out
2 of the hold tube.

3
4 Yet another aspect of the invention is, in a processor for commercially sterilizing a
5 liquid having an entry point and an exit point for the liquid, a hold tube between the entry and
6 exit points, a chamber holding steam adjacent the hold tube for indirectly heating the liquid in
7 the hold tube to a temperature of at least 130 °C for a time sufficient to commercially sterilize
8 the supplement while the supplement is passing through the hold tube, and a means for
9 restricting the flow of the liquid out of the processor, the improvement which comprises:

- 10 (a) increasing the thickness of the walls of the hold tube so that the hold tube
11 can withstand pressures up to 4,000 pounds per square inch;
12 (b) creating a continuous positive pressure through the system by the use of at
13 least one positive displacement pump controlled by a variable speed drive; and
14 (c) dynamically controlling the pump, the processor, and the means for
15 restricting the flow of the liquid out of the processor to ensure that the pressure
16 remains sufficiently high to keep the flow of the liquid through the hold tube
17 substantially turbulent.

18
19 A further aspect of the invention is, in a processor for commercially sterilizing a
20 liquid having a hold tube between the entry and exit points, and a chamber holding steam
21 adjacent the hold tube for indirectly heating the liquid in the hold tube to a temperature of at
22 least 130 °C for a time sufficient to commercially sterilize the supplement while the
23 supplement is passing through the hold tube, the improvement which comprises:

- 24 maintaining a pressure on the liquid through the hold tube which is higher than
25 the pressure on the steam in the chamber adjacent the hold tube, such that if a
26 leak in the hold tube develops, no steam will enter the hold tube and
27 contaminate the sterile liquid in the hold tube.

28 29 **DETAILED DESCRIPTION OF THE INVENTION**

30 The present invention is concerned with the formulation and manufacture of an
31 improved, commercially sterile liquid nutritional supplement. Thus, the description which
32 follows should be considered illustrative of a preferred embodiment and best mode for
33 practicing the invention, and not in any way a limit on the scope or applicability of the
34 various aspects of the invention herein.

35
36 In a preferred embodiment, the process for aseptically preparing and packaging the
37 improved liquid nutritional supplement of the present invention comprises (A) blending and

liquefying of ingredients to form an emulsion and (B) higher pressure sterilization by continuous thermal processing at ultra-high temperature followed by higher-pressure homogenization. The apparatus used to perform the various mechanical steps is any suitable equipment well-known to one skilled in the art, unless otherwise stated. This preferred process is discussed below.

A. Blending and Liquefying of Ingredients

One or more sources of proteins and one or more sources of carbohydrate are blended into a dry macro-nutrient mixture. Optionally, a stabilizer such as kappa-carrageenan and a wetting agent such as polysorbate 60 or 80 may be used. In a most preferred process, the protein is calcium sodium caseinates, and the carbohydrate is a fine sugar, which are used together with a stabilizer and a wetting agent in amounts as described below in Examples A and B. An alternative protein source is milk protein concentrate which has been subjected to ultrafiltration to reduce lactose. In a first mixing tank, this dry macro-nutrient mixture is then added to heated water and hydrated or solubilized into an aqueous formulation slurry.

Sources of minerals including potassium, calcium, magnesium, phosphorous and iron are blended into a dry mineral micro-nutrient mixture, and then mixed in water to form a mineral micro-nutrient slurry. This mineral micro-nutrient slurry is added to the aqueous formulation slurry. Most preferred sources and amounts of these minerals are described below in connection with Examples A and B.

Sources of trace minerals including iron, zinc, copper and iodine are blended into a dry trace mineral micro-nutrient mixture, and then mixed in water to form a trace mineral micro-nutrient slurry. A proper amount of the trace mineral micro-nutrient slurry is then added to the aqueous formulation slurry. Most preferred sources and amounts of these trace minerals are described below in connection with Examples A and B.

The pH of the nutrient slurry is then adjusted to about 6.9 to 7.0, or about 7.0 to 7.2 if an optional additional source of carbohydrate is added as discussed below. A source of fat is then added with agitation to form an emulsion with the aqueous nutrient slurry. The source of fat is most preferably one high in monounsaturated fatty acids, such as high oleic safflower oil, used in amounts as described below in connection with Examples A and B. Optionally, lecithin and vitamin E acetate can be added at this point to improve the emulsification and nutritional qualities of the supplement.

1 At this point, optionally an additional source of carbohydrate such as maltodextrin can
2 be added to the emulsified slurry. Butter flavor, a vitamin premix of the type well known in
3 the liquid nutritional supplement industry (such as those commercially available from
4 Hoffman LaRoche, Inc., of Nutley, New Jersey, for example), sodium ascorbate and if
5 desired chocolate flavor can be added to the emulsified slurry. The flavoring agents used
6 herein may be any of a number of flavoring agents well known in the nutritional supplement
7 industry (such as those commercially available from Universal Flavors, of Indianapolis,
8 Indiana, for example). After agitation, the total solids of the emulsified slurry are adjusted by
9 addition of water to not less than 30% of the total weight of the emulsified slurry. In the
10 alternative embodiment including the addition of maltodextrin, the total solids are adjusted to
11 not less than 38% of the total weight. Most preferred amounts of these ingredients are stated
12 below in connection with Examples A and B.

13
14 The solids-adjusted emulsified slurry is then passed through a tubular heat exchanger
15 to a second mixing tank, passing through a pump exerting a hydroshear on the slurry of from
16 between 100 to 250 psi. Alternatively, a homogenizer may be used in place of the hydroshear
17 pump. However, without wishing to be bound by theory, it is believed that the use of a pump
18 to hydroshear the emulsified slurry makes a more effective contribution than a homogenizer
19 to the maintenance of an emulsion during overnight storage and deaeration. It is also
20 believed that the use of a pump exerting a hydroshear to "deface" the supplement suspension
21 may extend the shelf life and control gellation in the final liquid nutritional supplement
22 product. In addition, a pump containing a hydroshear is easier to maintain and clean when
23 necessary than a standard homogenizer.

24
25 The slurry is then cooled and optionally flavored vanilla or strawberry to form the
26 final supplement mixture. In addition, the cooled supplement mixture may be refrigerated at
27 or below 7 °C and allowed to stand overnight (or at least 6 hours), which allows the
28 supplement mixture to deaerate. Without wishing to be bound by theory, it is believed that
29 this process of passing the emulsified slurry through a pump exerting a hydroshear and then
30 allowing the supplement mixture to stand overnight results in a supplement with extended
31 shelf life. Most preferred amounts of these ingredients and conditions of hydroshear and
32 storage are stated below in connection with Examples A and B.

33
34 The resulting nutritional supplement mixture is high in macro- and micro-nutrients,
35 and provides about 1.7 calories per milliliter (cal/ml). If the optional additional source of
36 carbohydrate is added, the supplement mixture provides about 2.0 cal/ml. Moreover, it is

1 much lower in sodium than liquid nutritional supplements not made according to the present
2 invention, as illustrated below in the Comparative Nutrient Values chart.

3
4 **B. Higher Pressure Sterilization and Homogenization**

5 The cooled final supplement mixture is subjected to continuous thermal processing at
6 ultra-high temperature (i.e., at a temperature of at least 130 °C) for a time sufficient to
7 commercially sterilize the supplement while the supplement is passing through a hold tube
8 under sufficient pressure to keep the flow of the supplement through the hold tube
9 substantially turbulent. To achieve the sterilization required by applicable Food and Drug
10 Administration regulations, the supplement mixture is exposed to temperature of about 140 to
11 145 °C in the hold tube for about 2 to 45 seconds. In a most preferred process, the
12 supplement is heated indirectly by steam while flowing through a spiral hold tube, the
13 sterilization temperature is about 142 to 144 °C, and the total time in the hold tube at
14 sterilization temperatures is 3 to 6 seconds. Alternatively, a straight or trombone-style tubing
15 system can be employed. As exposure to sterilization temperature causes some destruction of
16 the vitamins within the supplement mixture, the amount of vitamins added during
17 formulation can be adjusted for longer or shorter sterilization times so as to result in the
18 proper amount of vitamins in the final liquid nutritional supplement.

19
20 The UHT processing is performed using a Stork Sterideal Model 8000B indirect
21 continuous thermal processor which has been specially modified to generate and then to
22 withstand the pressure necessary to keep the flow through the processor substantially
23 turbulent. First, the processor has been modified by use of high-pressure tubing having walls
24 between 4.5 and 6 millimeters thick, and capable of withstanding pressures up to 4,000 psi.
25 Second, the Stork processor has also been modified to provide for continuous positive
26 pressure through the system by the use of one or more pumps having a variable speed drive
27 and positive displacement to push the supplement into the UHT processor. Third, these
28 pumps are dynamically controlled together with the modified Stork processor and a means
29 for controlling the flow of the supplement out of the processor (most preferably the higher-
30 pressure remote aseptic homogenizing valves (described below)) by the use of a computer to
31 ensure that the pressure remains sufficiently high to keep the flow of the supplement through
32 the hold tube substantially turbulent. In a most preferred process, the flow level is between
33 2,000 and 8,000 liters per hour. By the use of these modifications, the pressure within the
34 hold tube of the modified processor is not less than 2,800 psi, and the pressure drop through
35 the modified processor in the most preferred process is not greater than 500 psi. The
36 unmodified Stork Model 8000B is available from Stork Amsterdam of Amstelveen,
37 Netherlands.

1
2 The flow of the supplement through the tubing is considered "turbulent", as used
3 herein, if it contains at least some internal flow patterns in directions non-parallel to the
4 direction of flow of the supplement through the tubing. It is believed that this turbulent flow
5 prevents the localized build-up of heat and allows the sterilization heat to disperse more
6 evenly and rapidly throughout the supplement in the tube than non-turbulent, laminar flow.
7 Thus, it is believed that the turbulent flow of the supplement during UHT processing
8 contributes to the improved flavor profile and taste of the sterilized nutritional supplement,
9 and also prevents heat-induced emulsion instability which could lead to fouling of the UHT
10 processing system and shorten the expected shelf life of the packaged supplement.
11

12 The supplement is then subjected to a remote (i.e., after sterilization) aseptic
13 homogenizing valve creating a pressure of at least about 2,800 psi. Optionally, the
14 supplement is then passed through a second homogenizing valve creating a pressure of about
15 500 to 1,000 psi. In a most preferred process, the supplement is subjected to double-stage
16 "downstream" (i.e., after sterilization) homogenization at a first stage valve pressure of
17 approximately 3,100 psi, and a second stage valve pressure of about 500 psi. The first stage
18 homogenization valve also acts as a pressure restrictor on the supplement flow out of the
19 tubing of the modified Stork UHT processor, thereby (1) keeping the pressure within the hold
20 tube sufficiently high so that the flow of the supplement is substantially turbulent and
21 (2) eliminating the need for a separate "stuffer" pump to feed the supplement through the
22 homogenizing valves. Without being bound by theory, it is believed that pressures above
23 about 2,800 psi are more effective at homogenizing vegetable oils such as safflower oil,
24 which are the sources of fat used in nutritional supplements, than conventional pressures of
25 around 2,500 psi currently used in the nutritional supplement industry, which were designed
26 based on experiences with dairy products having milk fats.
27

28 As part of this higher pressure UHT processing, the supplement in the hold tube is at a
29 higher pressure than the steam in a chamber adjacent the hold tube used to indirectly heat the
30 supplement flowing through the hold tube to the sterilization temperature. Thus, if a small
31 leak in the tubing develops, no steam will enter the hold tube and contaminate the sterile
32 liquid in the hold tube. A small amount of supplement may escape into the adjacent steam,
33 but this will not affect the sterility of the supplement remaining in the hold tube and exiting
34 the processor. Moreover, because the pressure on the supplement increases as the supplement
35 passes through the hold tube, the sterile supplement toward the end of the hold tube is at a
36 higher pressure than the supplement which has just entered the processor. Upon entering the
37 processor, this non-sterile supplement may pass through tubing adjacent to the tubing holding

1 the outgoing sterile supplement in order to receive heat from the outgoing sterile supplement.
2 Thus, if a small leak develops in the tubing between the entering non-sterile supplement and
3 the exiting sterile supplement, the sterile supplement will not be contaminated by non-sterile
4 supplement. This ensures that the supplement remaining in the tube and exiting the processor
5 will be sterile, in compliance with applicable U.S. Food and Drug Administration
6 requirements, and thus will not need to be discarded.

7
8 As a result of this higher-pressure homogenization, the product is thoroughly
9 homogenized, resulting in reduction of droplet size as compared to liquid nutritional
10 supplements homogenized at lower pressures. The higher-pressure sterilization and
11 homogenization of the present invention leads to prolonged emulsion stability and expected
12 shelf life, and to a liquid product having superior mouth feel and flavor.

13
14 The following examples provide illustration of the invention but are not intended to
15 limit the scope of the invention hereto. Examples A and B are liquid nutritional supplements
16 formulated in accordance with most preferred embodiments of the instant invention. To
17 illustrate the improvement represented by the present invention, following Examples A and B
18 is a chart comparing the macro- and mineral micro-nutrient values of four ounces (118 ml) of
19 Example A with four ounces of two prior art supplements, TRAUMACAL available from
20 Mead Johnson & Co., and PULMOCARE available from Ross Laboratories, a division of
21 Abbot Laboratories, Inc.

22 23 Example A

24 To form the dry macro-nutrient mixture, 805 pounds (lbs) of calcium sodium
25 caseinate, 800 lbs of fine sugar, 2.6 lbs of polysorbate 80 and .84 lbs of kappa-carrageenan
26 are blended together. This dry macro-nutrient mixture is then added to 5,500 lbs of water
27 which has been pretreated through reverse osmosis and deionization, and heated to about 43 to
28 54 °C. This aqueous formulation slurry is then blended for 15 minutes.

29
30 To form the dry mineral micro-nutrient mixture, 32 lbs of dipotassium phosphate, 28
31 lbs of potassium citrate, 34 lbs of magnesium chloride, 5 lbs of magnesium carbonate, 5 lbs
32 of calcium phosphate (tribasic) and 6 lbs of calcium carbonate are added to 30 gallons of
33 pretreated water to form the mineral micro-nutrient slurry. The entire volume of this mineral
34 micro-nutrient slurry is then added to the aqueous formulation slurry.

35
36 The inventors have found the use of magnesium carbonate as a source of magnesium
37 to be particularly advantageous in the relatively concentrated liquid nutritional supplement of

1 the present invention, which has total solids of not less than 30% of the total weight of the
2 supplement. This is because, as a virtually water-insoluble compound, magnesium carbonate
3 does not tax the limited water available in the supplement. The inventors have found that the
4 magnesium carbonate can be kept in suspension over the expected shelf life of the product by
5 the use of a stabilizer, most preferably kappa-carrageenan. For the same reasons, the
6 inventors have found the use of calcium carbonate, another virtually water-insoluble source
7 of a mineral micro-nutrient, to be particularly advantageous. This source of calcium can also
8 be kept in suspension by the use of a stabilizer which is most preferably kappa-carrageenan.
9

10 To form the dry trace mineral micro-nutrient mixture, 544 grams (g) of ferric ortho-
11 phosphate, 454 g of zinc sulfate, 95 g of copper gluconate and 1.4 g of potassium iodide are
12 added to 1 gallon of pretreated water to form the trace mineral micro-nutrient slurry. The
13 entire volume of this trace mineral micro-nutrient slurry is then added to the aqueous
14 formulation slurry. The aqueous formulation slurry is then agitated and maintained at about
15 43 to 54 °C to solubilize and fully hydrate, or to suspend, the macro- and micro-nutrients in
16 the slurry.
17

18 The inventors have found the use of ferric ortho-phosphate as a source of iron to be
19 particularly advantageous for two reasons. One, it is virtually water-insoluble, and so does
20 not tax the limited water available in the relatively concentrated liquid nutritional supplement
21 of the present invention, as explained above. The inventors have found that it can be kept in
22 suspension by the use of a stabilizer, most preferably kappa-carrageenan. Two, it does not
23 cause discoloration of the liquid nutritional supplement during continuous thermal processing
24 at ultra-high temperatures. The inventors have determined that the use of ferrous sulfate,
25 which is commonly used in liquid nutritional supplements as a source of iron, causes the
26 liquid nutritional supplement to turn gray during UHT processing. This discoloration makes
27 the liquid nutritional supplement less appealing to the intended consumer and may require the
28 use of strong colorings in order to mask the discoloration. Without wishing to be bound by
29 theory, it is believed that the formation of iron sulfide during UHT processing causes this
30 discoloration.
31

32 Following the blending of the aqueous formulation slurry for 5 minutes, the pH is
33 adjusted to 6.9 to 7.0 with 20% potassium hydroxide. Then 830 lbs of high oleic safflower
34 oil, preheated to 93 °C are added to the aqueous formulation slurry. Vitamin E acetate in the
35 amount of 0.6 lbs and lecithin in the amount of 32 lbs are dissolved in 50 lbs of safflower oil
36 and added to the aqueous formulation slurry. The mixture is then agitated to further the
37 emulsification and blending process for about 15 minutes. Butter flavor (2.5 lbs), and a

1 vitamin dry mixture of 4.6 lbs of vitamin premix and 3.2 lbs of sodium ascorbate are added to
2 the emulsified slurry. The emulsified slurry is then blended for 5 minutes and the total solids
3 are adjusted to 31.5 % of the total weight of the emulsified slurry.

4
5 The emulsified slurry is then passed through a Moyno type pump exerting a
6 hydroshear between 195 to 205 psi at 150 gallons per minute and then cooled to about 22 °C.
7 The cooled slurry is then flavored with 23 lbs of vanilla flavoring to form the final
8 supplement mixture. The cooled supplement mixture is then refrigerated at 2-4 °C and
9 allowed to stand overnight before being subjected to UHT sterilization and aseptically
10 packaged.

11 12 Example B

13 To form the dry macro-nutrient mixture, 480 pounds (lbs) of calcium/sodium
14 caseinate, 550 lbs of fine sugar, 2.6 lbs of polysorbate 60 and 1.70 lbs of kappa-carrageenan
15 are blended together. This dry macro-nutrient mixture is then added to 4,400 lbs of water
16 which has been pretreated through reverse osmosis and deionization, and heated to about 43 to
17 54 °C. This aqueous formation slurry is then blended for 15 minutes.

18
19 To form the dry mineral micro-nutrient mixture, 15 lbs of dipotassium phosphate, 50
20 lbs of potassium citrate, 23 lbs of magnesium chloride, 1.0 lbs of calcium phosphate (tribasic)
21 and 20 lbs of calcium carbonate are added to 30 gallons of pretreated water to form the
22 mineral micro-nutrient slurry. The entire volume of this mineral micro-nutrient slurry is then
23 added to the aqueous formulation slurry.

24
25 To form the dry trace mineral micro-nutrient mixture, 272 grams (g) of ferric ortho-
26 phosphate, 227 g of zinc sulfate, 50 g of copper gluconate and 0.68 g of potassium iodide are
27 added to 1 gallon of pretreated water to form the trace mineral micro-nutrient slurry. The
28 entire volume of this trace mineral micro-nutrient slurry is then added to the aqueous
29 formulation slurry. The aqueous formulation slurry is then agitated and maintained at about
30 43 to 54 °C to solubilize and fully hydrate, or to suspend, the macro- and micro-nutrients in
31 the slurry.

32
33 Following the blending of the aqueous formulation slurry for 5 minutes, the pH is
34 adjusted to 7.1 to 7.2 with 20% potassium hydroxide. Then 710 lbs of high oleic safflower
35 oil, preheated to 93 °C are added to the aqueous formulation slurry. Vitamin E acetate in the
36 amount of 1.0 lbs and lecithin in the amount of 20 lbs are dissolved in 50 lbs of safflower oil
37 and added to the aqueous formulation slurry. The mixture is then agitated to further the

1 emulsification and blending process for about 15 minutes. Maltodextrin in the amount of
2 1,550 lbs is then added. Butter flavor (6.7 lbs), and a vitamin dry mixture of 2.5 lbs of
3 vitamin premix and 2.8 lbs of sodium ascorbate are added to the emulsified slurry. The
4 emulsified slurry is then blended for 5 minutes and the total solids are adjusted to 38.5 % of
5 the total weight of the emulsified slurry.

6
7 The emulsified slurry is then passed through a Moyno type pump exerting a
8 hydroshear between 195 to 205 psi at 150 gallons per minute and then cooled to about 22 °C.
9 The cooled slurry is then flavored with 23 lbs of vanilla flavoring to form the final
10 supplement mixture. The cooled supplement mixture is then refrigerated at 2-4 °C and
11 allowed to stand overnight before being subjected to UHT sterilization and aseptically
12 packaged.
13

1 **Comparative Macro- and Mineral Micro-Nutrient Values***

| Composition | Example A | | TRAUMACAL | | PULMOCARE | |
|--------------|-----------|-----------------|-----------|-----------------|-----------|-----------------|
| | Amount | % Daily Value** | Amount | % Daily Value** | Amount | % Daily Value** |
| Calories | 200 | *** | 178 | *** | 178 | ** |
| Protein | 10 g | 20 | 9.8 g | 19.5 | 7.4 g | 17 |
| Fat | 13 g | 20 | 8.1 g | 12.5 | 11.05 g | 4 |
| Carbohydrate | 11 g | 4 | 17.0 g | 5.5 | 12.5 g | 4 |
| Sodium | 65 mg | 3 | 140 mg | 6.0 | 155 mg | 6.5 |
| Potassium | 380 mg | 10 | 165 mg | 4.5 | 205 mg | 6 |
| Calcium | 206 mg | 20 | 88.5 mg | 9.0 | 125 mg | 12.5 |
| Magnesium | 82 mg | 20 | 23.5 mg | 6.0 | 50 mg | 12.5 |
| Phosphorus | 210 mg | 20 | 88.5 mg | 9.0 | 125 mg | 12.5 |
| Iron | 4.4 mg | 20 | 1.05 mg | 6.0 | 2.25 mg | 12.5 |
| Copper | 0.42 mg | 20 | 0.175 mg | 9.0 | 0.25 mg | 12.5 |
| Zinc | 3.2 mg | 20 | 1.75 mg | 12 | 2.8 mg | 18 |
| Iodine | 33.0 mcg | 20 | 8.85 mcg | 6.0 | 18.75 mcg | 12.5 |

2
3 * The values for 4 fluid ounces of TRAUMACAL and PULMOCARE are calculated
4 based on the label information given for 8 fluid ounces (236 ml) of those prior art
5 supplements.

6 ** Percent Daily Values are based on a 2,000 calorie diet.

7 *** The U.S. Food and Drug Administration has not established % Daily Value.

8
9 Thus, an improved liquid nutritional supplement having improved flavor profile and
10 taste which provides improved concentration of many recommended macro- and micro-
11 nutrients in a shelf-stable form has been provided. One skilled in the art will appreciate that
12 the present invention can be practiced by other than the described embodiments, which are
13 presented here for purposes of illustration and not of limitation, and that the present invention
14 is limited only by the claims that follow.

WHAT IS CLAIMED:

1. A liquid nutritional supplement comprising:
 - (a) a macro-nutrient component comprising 22 to 150 milligrams of protein and 30 to 200 milligrams of fat per milliliter of supplement; and
 - (b) a mineral micro-nutrient component comprising 1.5 to 10 milligrams of potassium; 0.4 to 2.97 milligrams of calcium; 0.17 to 1.18 milligrams of magnesium; 0.42 to 2.97 milligrams of phosphorus; and 0.015 to 0.053 milligrams of iron per milliliter of supplement;wherein the nutritional supplement is commercially sterile and shelf-stable.
2. The liquid nutritional supplement of claim 1, wherein the macro-nutrient component further comprises 50 to 350 milligrams of carbohydrate and the total solids present in the supplement is not less than 30% of the total weight of the supplement.
3. The liquid nutritional supplement of claim 2, wherein:
 - (a) the macro-nutrient component comprises about 85 milligrams of protein, about 110 milligrams of fat, and about 93 milligrams of carbohydrate per milliliter of supplement; and
 - (b) the mineral micro-nutrient component comprises about 3.2 milligrams of potassium; about 1.75 milligrams of calcium; about 0.69 milligrams of magnesium; about 1.78 milligrams of phosphorus; and about 0.037 milligrams of iron per milliliter of supplement.
4. The liquid nutritional supplement of claim 2, wherein:
 - (a) the macro-nutrient component comprises about 51 milligrams of protein, about 93 milligrams of fat, and about 237 milligrams of carbohydrate per milliliter of supplement; and
 - (b) the mineral micro-nutrient component comprises about 3.2 milligrams of potassium; about 1.75 milligrams of calcium; about 0.34 milligrams of magnesium; about 0.89 milligrams of phosphorus; and about .0195 milligrams of iron per milliliter of supplement.
5. A commercially sterile and shelf-stable liquid nutritional supplement comprising
 - (a) a macro-nutrient component comprising at least one source of protein, at least one source of fat, and at least one source of carbohydrate,
 - (b) a mineral micro-nutrient component comprising at least one source of mineral micro-nutrients which is virtually water-insoluble, and
 - (c) a stabilizer,

1 wherein the total solids present in the supplement is not less than 30% of the
2 total weight of the supplement.

3 6. The liquid nutritional supplement of claim 5, wherein the virtually water-
4 insoluble source of mineral micro-nutrients is selected from the group consisting of
5 magnesium carbonate, ferric ortho-phosphate, and calcium carbonate.

6 7. The liquid nutritional supplement of claim 5, wherein the supplement is
7 sterilized at least in part by continuous thermal processing at a temperature of at least 130 °C
8 for a time sufficient to commercially sterilize the supplement.

9 8. The liquid nutritional supplement of claim 5 wherein a source of protein is
10 calcium sodium caseinates.

11 9. The liquid nutritional supplement of claim 5 wherein a source of protein is
12 milk protein concentrate which has been subjected to ultrafiltration to reduce lactose.

13 10. The liquid nutritional supplement of claim 5 wherein a source of fat is high in
14 monounsaturated fatty acids.

15 11. The liquid nutritional supplement of claim 10 wherein a source of fat is high
16 oleic safflower oil.

17 12. The liquid nutritional supplement of claim 5 wherein the source of
18 carbohydrate is fine sugar, and the pH is adjusted to about 6.9 to 7.0.

19 13. The liquid nutritional supplement of claim 5 wherein a source of carbohydrate
20 is fine sugar, an additional source of carbohydrate is maltodextrin, the pH is adjusted to about
21 7.0 to 7.2, and the total solids are not less than 38% of the total weight of the supplement.

22 14. The liquid nutritional supplement of claim 5 wherein the stabilizer is kappa-
23 carrageenan.

24 15. The liquid nutritional supplement of claim 5 further comprising a wetting
25 agent.

26 16. The liquid nutritional supplement of claim 15 wherein the wetting agent is
27 selected from the group consisting of polysorbate 60 and polysorbate 80.

28 17. The liquid nutritional supplement of claim 5 wherein the mineral micro-
29 nutrient component comprises sources of potassium, calcium, magnesium, phosphorous and
30 iron.

31 18. The liquid nutritional supplement of claim 17, wherein the mineral micro-
32 nutrient sources are selected from the group consisting of dipotassium phosphate, potassium

1 citrate, magnesium chloride, magnesium carbonate, calcium phosphate (tribasic) and calcium
2 carbonate.

3 19. The liquid nutritional supplement of claim 5 further comprising a trace
4 mineral micro-nutrient component comprising at least one source of iron, zinc, copper and
5 iodine.

6 20. The liquid nutritional supplement of claim 19 wherein the sources of trace
7 mineral micro-nutrients are ferric ortho-phosphate, zinc sulfate, copper gluconate, and
8 potassium iodide.

9 21. The liquid nutritional supplement of claim 5 further comprising lecithin,
10 vitamin E acetate, flavorings, vitamins and sodium ascorbate.

11 22. The liquid nutritional supplement of claim 5 wherein the supplement provides
12 at least about 1.7 calories per milliliter.

13 23. The liquid nutritional supplement of claim 13 wherein the supplement
14 provides at least about 2.0 calories per milliliter.

15 24. A liquid nutritional supplement sterilized by continuous thermal processing at
16 ultra-high temperature comprising as a source of iron ferric ortho-phosphate.

17 25. A process for maintaining emulsion stability and extending the shelf life of a
18 liquid nutritional supplement formulated as an emulsified slurry comprising sources of
19 macro-nutrients and then sterilized, comprising the step of passing the emulsified slurry
20 through a pump exerting a hydroshear of between 100 to 250 pounds per square inch.

21 26. The process of claim 25, further comprising the steps of

22 (a) cooling the supplement to a temperature below about 7 °C and

23 (b) allowing the supplement to stand for not less than 6 hours before sterilizing
24 the supplement.

25 27. The process of claim 25 wherein the pump is exerting a hydroshear of between
26 195 to 205 pounds per square inch.

27 28. A process for aseptically sterilizing and homogenizing a liquid nutritional
28 supplement comprising the steps of:

29 (a) heating the supplement to a temperature of at least 130 °C for a time
30 sufficient to commercially sterilize the supplement while the supplement is passing
31 through a hold tube under a pressure sufficient to keep the flow of the supplement
32 through the hold tube substantially turbulent;

(b) passing the supplement through a remote aseptic homogenizer having at least one valve creating a pressure of at least 2,800 pounds per square inch wherein the valve also acts as a pressure restrictor on the supplement flow out of the hold tube.

29. The process of claim 28, wherein the supplement is heated indirectly while flowing through a spiral hold tube.

30. The process of claim 29, wherein the supplement mixture is heated to a temperature of about 140 - 145 °C for about 2 to 45 seconds.

31. The process of claim 30, wherein the supplement mixture is heated to a temperature of about 142 - 144 °C for about 3 to 6 seconds.

32. The process of claim 28, wherein the supplement is passed through a second remote aseptic homogenizing valve creating a pressure of at least about 500 pounds per square inch.

33. The process of claim 32, wherein the supplement is passed through a double stage homogenizer having a first stage valve creating a pressure of 3,100 pounds per square inch and a second stage valve pressure creating a pressure of 500 pounds per square inch.

34. In a processor for commercially sterilizing a liquid having an entry point and an exit point for the liquid, a hold tube between the entry and exit points, a chamber holding steam adjacent the hold tube for indirectly heating the liquid in the hold tube to a temperature of at least 130 °C for a time sufficient to commercially sterilize the supplement while the supplement is passing through the hold tube, and a means for restricting the flow of the liquid out of the processor, the improvement which comprises:

(a) increasing the thickness of the walls of the hold tube so that the hold tube can withstand pressures up to 4,000 pounds per square inch;

(b) creating a continuous positive pressure through the system by the use of at least one positive displacement pump controlled by a variable speed drive; and

(c) dynamically controlling the pump, the processor, and the means for restricting the flow of the liquid out of the processor to ensure that the pressure remains sufficiently high to keep the flow of the liquid through the hold tube substantially turbulent.

35. The processor of claim 34, wherein the flow level of the liquid through the processor is between 2,000 and 8,000 liters per hour.

36. The processor of claim 34, wherein difference in pressure on the liquid at the entry point and the exit point is not more than 500 pounds per square inch.

1 37: The processor of claim 34, wherein the pressure within the hold tube is not
2 less than 2,800 pounds per square inch.

3 38. In a processor for commercially sterilizing a liquid having a hold tube between
4 the entry and exit points, and a chamber holding steam adjacent the hold tube for indirectly
5 heating the liquid in the hold tube to a temperature of at least 130 °C for a time sufficient to
6 commercially sterilize the supplement while the supplement is passing through the hold tube,
7 the improvement which comprises:

8 maintaining a pressure on the liquid through the hold tube which is higher than
9 the pressure on the steam in the chamber adjacent the hold tube, such that if a leak in
10 the hold tube develops no steam will enter the hold tube and contaminate the liquid in
11 the hold tube.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21303**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :Please See Extra Sheet.

US CL :Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/2, 8, 905; 426/72, 74, 590, 601, 656, 658; 366/136, 159, 160.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS, STN MEDICINE CLUSTER

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------------|---|--|
| X ---- Y | US 5,108,767 A (MULCHANDANI et al) 28 April 1992, Cols. 5-6. 1, 3-4, 9-10, 12-14, 19 | 1-2, 5-7, 9-13, 17, 19, 21-23, 28, 32 ----- 3-4, 8, 18, 24 |
| X ---- Y | US 5,340,603 A (NEYLAN et al) 23 August 1994, Cols. 9, 20-22. 1-6, 12-13 | 5-7, 10-11, 17, 19, 21 ----- 1-4, 14, 18, 20, 24 |

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

| | |
|---|--|
| * Special categories of cited documents: | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" document defining the general state of the art which is not considered to be of particular relevance | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" earlier document published on or after the international filing date | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "A" document member of the same patent family |
| "O" document referring to an oral disclosure, use, exhibition or other means | |
| "P" document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search

05 FEBRUARY 1998

Date of mailing of the international search report

26 FEB 1998

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21303

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------------|--|--|
| X ----- Y | US 5,545,411 A (CHANCELLOR) 13 August 1996, Cols. 1-6. | 1-2, 5, 8-14, 17-19, 28, 32-33 ----- 3-4, 18, 25, 27 |
| X ----- Y | US 5,472,952 A (SMIDT, et al) 05 December 1995, Cols. 8-9. | 1-2, 5, 10-11, 17, 19 ----- 3-4, 6, 8, 18, 20 |
| X ----- Y | US 5,520,948 A (KVAMME) 28 May 1996, Cols. 1-4. 8-9, 11-12 | 5, 8, 10-11, 17, 19 ----- 28, 32 |
| Y | US 4,419,369 A (NICHOLS et al) 06 December 1983, Col. 3, lines 16-18. | 8 |
| Y | GB-1135552 A (PFIZER & CO INC) 31 August 1993, Abstract. | 6, 20, 24 |
| A | US 4,591,463 (NAHRA, et al) 27 May 1986, Entire Document | 34-38 |
| A | US 4,844,620 A (LISSANT, et al) 04 July 1989, Entire Document | 34-38 |
| A | US 5,378,488 A (DIMLER et al) 03 January 1995, Cols. 1-4. | 34-38 |
| A,P | US 5,656,317 A (SMITS et al) 12 August 1997, Entire Document | 34-38 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21303

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

A. CLASSIFICATION OF SUBJECT MATTER:

IPC (6):

A01N 37/18; A61K 38/00, 38/16; A23D 7/00, 9/00; A23G 3/00; A23J 1/00; A23L 1/30, 2/00; A23K 1/175; B01F 15/02; G05D 11/00

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

514/2, 8, 905; 426/72, 74, 590, 601, 656, 658; 366/136, 159, 160.2

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group

I, claim(s) 1-24, drawn to a liquid nutritional supplement.

Group II, claim(s) 26-33, drawn to a process for maintaining emulsion stability and extending shelf life.

Group III, claim(s) 34-38, drawn to an improvement in a processor for commercially sterilizing a liquid.

The inventions listed as Groups I, II, and III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the composition is its own distinct invention and the special technical feature of the composition is not required by Groups II and III. Additionally, the claimed apparatus, Group III is not specially adapted for the process of Group II.

The base claim of group II mentions a liquid nutritional supplement but it does not have to be the same liquid nutritional supplement claimed. This emulsification process could be applied to nutritional supplements other than those claimed by applicants, infant formula, dairy products and non-dairy creamers.

The apparatus of Group III does not have to be used in the process of Group II. Group II specifically deals with nutritional supplements while Group III is any liquid.